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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/903,943	07/11/2001	Avi Ashkenazi	10466/88	1367

35489 7590 11/06/2003

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EXAMINER

KAUFMAN, CLAIRE M

ART UNIT PAPER NUMBER

1646

DATE MAILED: 11/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b>	Application No. 09/903,943	Applicant(s) ASHKENAZI ET AL.	
	Examiner Claire M. Kaufman	Art Unit 1646	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 02 October 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 02 October 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☒ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached sheet.
6. ☒ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_

Claim(s) objected to: \_\_\_\_\_

Claim(s) rejected: 39-44.

Claim(s) withdrawn from consideration: \_\_\_\_\_

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
10. ☐ Other: \_\_\_\_\_

**Continuation of Advisory Action:**

*Continuation of #6:*

37 CFR § 1.195 Affidavits or declarations after appeal:

Affidavits, declarations, or exhibits submitted after the case has been appealed will not be admitted without a showing of good and sufficient reasons why they were not earlier presented.

[34 FR 18858, Nov. 26, 1969]

It is stated in MEPE § 1208 that:

If an affidavit, declaration, or exhibit was refused entry under 37 CFR 1.195, the examiner should not comment on it in the examiner's answer. Likewise, it would be improper for appellant to rely on an affidavit, declaration, or exhibit, which was refused entry, in an appeal brief. If appellant has grounds for challenging the non-entry of an affidavit, declaration, or exhibit, he or she should file a timely petition seeking supervisory review of the non-entry.

In the instant case there is not sufficient showing of good and sufficient reasons why the Declaration of Ashkenazi and References accompanying the Appeal Brief were not earlier presented. As a result, neither the declaration nor any of the references not previously submitted (see page 2, ¶ 6) will be entered or considered.

*Continuation of #5:*

The specification provides no identification of the chromosome to which the nucleic acid encoding PRO339 maps. Testing for chromosomal aneuploidy is an invitation for further experimentation. Also, there is no evidence that clinicians use information about a gene product not-being overexpressed as a basis for deciding to not treat a patient with an agent that targets that gene product. This is a hypothetical utility not disclosed in the specification. As to evidentiary standard, since there is no control for aneuploidy, it is maintained that the skilled artisan cannot reasonably conclude that a gene product is overexpressed, particularly when the level of overexpression was detected at only 2-3 fold. However, even if the nucleic acid encoding the PRO protein had utility, the antibody that binds the protein would not because it cannot be used diagnostically.

The response has not overcome the rejections under 35 USC 102 and 103 because the specification does not support the limiting definition for specific binding that Applicants argue. Further, while Applicants present one dictionary definition that limits such binding to "having an affinity limited to a particular... antigen," that could be construed as meaning a high affinity for a particular antigen but lower affinities for others could exist. Additionally, it is acknowledged that reference to an epitope tag generally have at least six amino acids is for a "tag polypeptide". However the tag is fused to a PRO polypeptide and supports making antibodies to small portions of a larger polypeptide. For these reasons and those of record, the claims remain rejected over the prior art.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (703) 305-5791. Dr. Kaufman can generally be reached Monday through Thursday from 8:30AM to 12:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (703) 308-6564.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

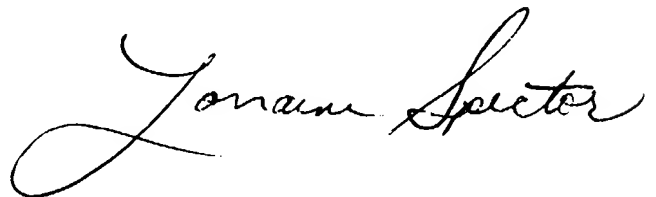
Official papers filed by fax should be directed to (703) 872-9306. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office

Claire M. Kaufman, Ph.D.



Patent Examiner, Art Unit 1646

November 4, 2003



**LORRAINE SPECTOR  
PRIMARY EXAMINER**